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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,124	11/19/2001	Robert L. Campbell	P-5277	4642

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,124	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *3,22-29,34,38-40,45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-21,30-33,35-37,41-44 and 47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040510*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of the species (d) xkxxx and the sequence SEQ ID NO:34 in the reply filed on September 20, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 22-29, 34, 38-40, 45, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected sequence. Election was made **without** traverse in the reply filed on September 20, 2004.

2. The Sequence Listing filed November 20, 2002 was approved by STIC for matters of form.

3. The disclosure is objected to because of the following informalities: There is no Brief Description of the new figure filed September 20, 2004. See 37 CFR 1.74. Appropriate correction is required.

34. The amendment filed September 20, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The new sheet of drawings contains new matter in the entry for h-collagen I. In Table 1, the Abs at 590 nm for this protein is given as 1.79, whereas in Figure 1 the value is given as 1.80.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. Claims 4, 30-32, 35, 41, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The elected sequence, HKNQT, is not the same as SEQ ID

NO:34 as defined in the Sequence Listing filed November 20, 2002. Note that in the Sequence Listing, the amino acid at position 5 is Tyr/Y, rather than Thr/T. It is not clear which sequence was intended by Applicants.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 2, 4, 6-13, 15, 19, 30-32, 41, 42, and 49-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/259,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '816 application claims the peptides KKKK, DDEEK, KLMSY, and FFFKK, which anticipate the instant claimed peptides. The claims of the '816 application recite the use of the peptides as a coating for biomedical devices. The claimed peptides, either alone or in combination with the other claimed peptides of the '816 application, also constitute a peptide library. In view of the similarity in structure between the peptides claimed in the '816 application and the instant claimed peptides, inherently the peptides claimed in the '816 application will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient

evidence of similarity is deemed to be present between the peptides claimed in the '816 application and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the '816 application. With respect to, e.g., claims 5-7, 10, 19, 32, 51, and 52, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 2, 5-7, 10-12, 19, and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,759,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '510 patent anticipate the instant claims. In particular the '510 patent claims SEQ ID NOS:25, 30, 34, 40, 53-55, 58, 62, 70-72, 79-81, and 86-88, which have the same structure as is recited in the instant claims. The claimed peptides, either alone or in combination with the other claimed peptides of the '510 patent, also constitute a peptide library. In view of the similarity in structure between the peptides claimed in the '510 patent and the instant claimed peptides, inherently the peptides claimed in the '510 patent will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides claimed in the '510 patent and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of the '510 patent. With respect to, e.g., claims 5-7, 10, and 19, an intended use

limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

9. Claims 1, 2, 5-17, 19-21, 33, 36, 37, 42-44, and 48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/641,286. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '286 application anticipate the instant claims. See especially SEQ ID NOS: 1-3, 5-13, 15, and 16 of the '286 application. Note that the CAR material can be a polysaccharide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 2, 5-17, 19-21, 33, 36, 37, 42-44, and 48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 10/670,771. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '771 application anticipate the instant claims. See especially SEQ ID NOS: 1-3, 5-13, 15, and 16 of the '771 application. Note that the CAR material can be a polysaccharide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1, 2, 5-7, 10-12, 19, and 42 are directed to an invention not patentably distinct from claim 1 of commonly assigned U.S. Patent No. 6,759,510. Specifically, see the above obviousness-type double patent rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,759,510, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 2, 5-13, 19-21, 33, 36, 37, 42, 44, and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by the Tong et al article (Biomaterials, Vol. 22, pages 1029-1034). The Tong

et al article teaches neurons cultured on a surface comprising an FEP film modified with the peptide SIKVAV. The presence of the peptide improved neurite outgrowth and adhesion. See, e.g., the Abstract. The peptide SIKVAV comprises the elected structure xkxxx. The peptide SIKVAV, either alone or in combination with the other peptides discussed by the Tong et al article, also constitutes a peptide library. With respect to instant claims 5-7, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by or obvious over the prior art. With respect to instant claim 11, in view of the similarity in structure and function between the peptide of the Tong et al article and Applicants' claimed peptide, inherently the peptide of the Tong et al article will increase the oxygen consumption of some cell to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of the Tong et al article and Applicants' claimed peptide to shift the burden to Applicants to provide evidence that the claimed peptide is unobviously different than that of the Tong et al article.

14. Claims 1, 2, 5-7, 10-12, 19, 42, 44, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,759,510. See the above obviousness-type double patenting rejection. In addition, the '510 patent teaches the use of the peptides in cell cultures. See, e.g., column 8, lines 16-31.

15. Claims 1, 2, 4-7, 10-12, 19, 30, 32, 41, 42, and 49-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyazaki et al (U.S. Patent No. 5,411,956). Miyazaki et al teach the peptide α-(L-lysine)$_5$ (see Table 6), which has the same structure as is recited in instant claims 1, 49, and 50. The peptide, either alone or in combination with the other disclosed peptides of Miyazaki et al, also constitutes a peptide library. In view of the similarity in structure between

the peptide of Miyazaki et al and the instant claimed peptides, inherently the peptide of Miyazaki et al will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of Miyazaki et al and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than that of Miyazaki et al. With respect to, e.g., claims 5-7, 10, 19, 32, 51, and 52, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

15. Claims 1, 2, 4-7, 10-12, 19, 30, 32, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Cahoon et al (U.S. Patent No. 6,552,249). Cahoon et al teach a soybean cinnamyl-alcohol dehydrogenase polypeptide comprising the sequence HKNQY. See, e.g., column 2, lines 4-6, and SEQ ID NO:34, residues 22-26. The polypeptide, either alone or in combination with the other disclosed polypeptides of Cahoon et al, also constitutes a peptide library. In view of the similarity in structure between the peptide of Cahoon et al and the instant claimed peptides, inherently the peptide of Cahoon et al will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of Cahoon et al and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than that of Cahoon et al. With respect to, e.g., claims 5-7, 10, 19, and 32, an intended use limitation does not impart patentability to product

claims where the product is otherwise anticipated or obvious. With respect to instant claims 4, 30, and 41, this rejection assumes that Applicants intended to claim HKNQY instead of HKNQT (see the above rejection under 35 U.S.C. 112, second paragraph), and that the claims embrace polypeptides which comprise the partial sequence HKNQY instead of being limited to pentapeptides consisting of the sequence HKNQY.

16. Claims 1, 2, 5-17, 19, 42-44, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierschbacher et al (U.S. Patent No. 5,955,578). Pierschbacher et al teach a matrix comprising peptides comprising an xxxxk structure, conjugated to hyaluronic acid or chondroitin sulfate. The matrix provides binding sites for cells during wound healing. The matrix can be coated onto a biodegradable material or other implanted material. See, e.g., column 2, line 66 - column 3, line 22; column 5, lines 13-16; and claims 1 and 6-8. Hyaluronic acid and chondroitin sulfate are polysaccharides. The conjugated peptides, either individually or in combination with the other disclosed conjugated peptides of Pierschbacher et al, also constitute a peptide library. In view of the similarity in structure between the peptides of Pierschbacher et al and the instant claimed peptides, inherently the peptides of Pierschbacher et al will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the conjugated peptides of Pierschbacher et al and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of Pierschbacher et al. With respect to, e.g., claims 5-7, an intended use limitation

does not impart patentability to product claims where the product is otherwise anticipated or obvious.

17. Claims 1, 2, 5-7, 10-12, 16, 18, 19, 42, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruoslahti et al (U.S. Patent Application Publication 2003/0045476). Ruoslahti et al teach a peptide of SEQ ID NO:10, which comprises a xkxxx structure, linked to VEGF. See, e.g., claims 20 and 22. The conjugated peptides, either individually or in combination with the other disclosed conjugated peptides of Ruoslahti et al, also constitute a peptide library. In view of the similarity in structure between the peptides of Ruoslahti et al and the instant claimed peptides, inherently the peptides of Ruoslahti et al will enhance cell growth and/or secretion in a cell culture system, will promote adherence of anchorage-dependent cells on a surface, and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the conjugated peptides of Ruoslahti et al and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of Ruoslahti et al. With respect to, e.g., claims 5-7, 10, and 19, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

18. Claims 1, 2, 5-13, 15, 19, 33, 42, 44, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Clapper et al (U.S. Patent No. 6,121,027). Clapper et al teach culturing calf pulmonary artery endothelial cells in culture plates in which polymers with immobilized peptides are placed. All of the peptides comprise at least one of the structures recited in Applicants' claim 1. The cells adhere onto the immobilized peptides, and the cells' growth is enhanced. See Example 1. The immobilized peptides, either individually or in combination with the other

disclosed immobilized peptides of Clapper et al, also constitute a peptide library. In view of the similarity in structure between the peptides of Clapper et al and the instant claimed peptides, inherently the peptides of Clapper et al will enhance secretion in a cell culture system and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the immobilized peptides of Clapper et al and the instant claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of Clapper et al. With respect to, e.g., claims 5-7, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

19. Claims 1, 2, 5-17, 19-21, 33, 36, 37, 42-44, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellamkonda et al (U.S. Patent No. 5,834,029). Bellamkonda et al teach nerve guide channels comprising a tubular semipermeable membrane with a bioartificial three-dimensional hydrogel extracellular matrix dispersed therein. The hydrogel can be comprised of a polysaccharide such as agarose. A peptide comprising the partial sequence IKVAV is attached to the matrix. Nerve growth factor may also be provided in the hydrogel. See, e.g., column 9, lines 37-45, and claims 1 and 4-6. The immobilized peptides, either individually or in combination with the other disclosed immobilized peptides of Bellamkonda et al, also constitute a peptide library. In view of the similarity in structure between the peptides of Bellamkonda et al and the instant claimed peptides, inherently the peptides of Bellamkonda et al will enhance secretion in a cell culture system and will increase oxygen consumption of cells to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the immobilized peptides of Bellamkonda et al and the instant claimed peptides to shift the

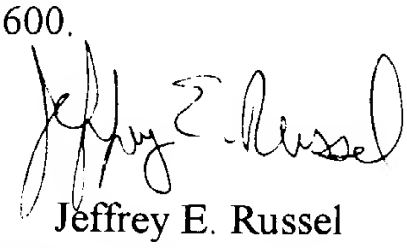
burden to Applicants to provide evidence that the claimed peptides are unobviously different than those of Bellamkonda et al. With respect to, e.g., claims 5-7, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated or obvious.

20. It should be noted that the search of the elected sequence was carried out on the basis of the sequence listing filed November 20, 2002, i.e. the sequence HKNQY was searched in the various sequence databases. If Applicants decide that HKNQT is the intended sequence, then after submission and approval of a corrected sequence listing, a new sequence search will be required. It should be noted that the identity of the sequence does not involve issues of new matter, because the sequence listing originally filed with the application on November 19, 2001 also defines SEQ ID NO:34 as HKNQY.

21. Furcht et al (U.S. Patent No. 5,294,551) is cited as art of interest, being essentially duplicative of the references applied above.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



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October 29, 2004